

**IN THE UNITED STATES DISTRICT CIRCUIT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

KATHLEEN BIESTERFELD, Individually)
as Mother & Next Best Friend of)
NICHOLAS BIESTERFELD, and)
RONALD BIESTERFELD,)

Plaintiffs,)

v.)

Case No. 1:21-cv-03085
Judge Edmond E. Chang

ARIOSIA DIAGNOSTICS, INC.; ARIOSIA)
DIAGNOSTICS CLINICAL)
LABORATORY; and HARMONY)
PRENATAL TESTING,)

Defendants.)

FIRST AMENDED COMPLAINT AT LAW

NOW COME the Plaintiffs, KATHLEEN BIESTERFELD, Individually as Mother & Next Best Friend of NICHOLAS BIESTERFELD, and RONALD BIESTERFELD, by their attorneys, VINKLER LAW OFFICES, LTD., and complaining of the Defendants ARIOSIA DIAGNOSTICS, INC.; ARIOSIA DIAGNOSTICS CLINICAL LABORATORY; and HARMONY PRENATAL TESTING allege as follows:

I. INTRODUCTION

1. This action is brought pursuant to the laws of the State of Illinois to redress personal injury and economic loss sustained by what is termed under Illinois law as “wrongful birth” for extraordinary expenses and emotional distress.

II. JURISDICTION

2. Jurisdiction is based on Title 20 U.S.C. §1332. The parties are citizens of different states and the amount in controversy is in excess of \$75,000.

3. At all times Plaintiffs KATHLEEN BIESTERFELD and RONALD BIESTERFELD resided in the City of Roselle, County of DuPage, State of Illinois.
4. Defendant ARIOSIA DIAGNOSTICS, INC. is a corporation headquartered in the City of San Jose, County of Santa Clara, State of California.
5. ARIOSIA DIAGNOSTICS CLINICAL LABORATORY is a division of ARIOSIA DIAGNOSTICS, INC. (collectively “ARIOSIA”) and is also located in the City of San Jose, County of Santa Clara, State of California.
6. Defendants engage in continuous trade and commerce in Illinois including all counties, by marketing and selling prenatal test kits claimed to detect Down Syndrome and other genetic abnormalities to customers and ultimate consumers such as the BIESTERFELDS through physicians in Illinois.
7. The BIESTERFELDS purchased a product of ARIOSIA in Illinois.

III. FACTS COMMON TO ALL COUNTS

8. Plaintiffs KATHLEEN BIESTERFELD and RONALD BIESTERFELD became pregnant with their first child in 2017. They sought prenatal care through DuPage Medical Group’s OBY-GYN clinic (“DMG”) and saw Dr. Mitchell, Dr. Wirth and Dr. Patsavas of DMG.
9. As KATHLEEN BIESTERFELD was 35 at the time, the BIESTERFELDS requested genetic testing be performed by their doctors to determine the presence of Down Syndrome (Trisomy 21 defect) or another genetic abnormality. They were prepared to abort the pregnancy should they learn there was present Down Syndrome.
10. The doctors at DMG offered and recommended a genetic test from ARIOSIA called the Harmony Prenatal Test (“ARIOSIA Test”).

11. The doctors at DMG orally represented to the BIESTERFELDS they were told by ARIOSAs that the test was 100% accurate. In addition, the doctors at DMG provided to the BIESTERFELDS an ARIOSAs brochure for marketing from ARIOSAs.
12. The BIESTERFELDS then went home and researched the accuracy of the ARIOSAs test, and found on ARIOSAs website a page that represented, advertised, boasted, and guaranteed the ARIOSAs Test had a 100% accuracy rate in detecting Trisomy 21.
13. The BIESTERFELDS concluded based on review of all the information provided by ARIOSAs that the ARIOSAs Test had a 100% accuracy rate and relied on the representations of ARIOSAs through the doctors at DMG, the ARIOSAs brochure, and the ARIOSAs website.
14. ARIOSAs advertising was deceptive on its face as ARIOSAs knew the combination of the training it provided to doctors, along with its brochures and on-line advertising, would provide a net impression to consumers and the general populace the ARIOSAs Test was 100% accurate.
15. The BIESTERFELDS, as a pregnant couple near or over 35 and concerned about genetic defects more prevalent to older mothers, were the very consumers ARIOSAs targeted by its advertising and marketing.
16. The BIESTERFELDS then requested that the doctors at DMG order and administer the ARIOSAs Test.
17. The ARIOSAs Test is performed by a blood draw from the arm. It costs over \$400. After the BIESTERFELDS asked DMG to perform the ARIOSAs Test, the Test was ordered by Dr. Patsavas and blood was collected on July 18, 2017 at the DMG clinic in Downers Grove, Illinois. The blood was then sent to the ARIOSAs labs in San Jose, California.

18. DMG charged the BIESTERFELDS for the ARIOSIA Test. As the BIESTERFELDS had the forethought to obtain medical insurance, DMG agreed to accept payment direct through the BIESTERFELD'S insurer instead of requesting the BIESTERFELDS pay for the ARIOSIA Test first and later request reimbursement from their insurer.
19. The BIESTERFELDS became consumers of the ARIOSIA Test when they requested that the doctors at DMG order and administer the ARIOSIA Test, and later paid for it.
20. DMG received the results of the ARIOSIA Test July 23, 2017. The DMG clinic reported to MRS. BIESTERFELD via telephone the ARIOSIA Test was negative.
21. The BIESTERFELDS were lead to believe by ARIOSIA, and did believe, that the ARIOSIA Test was 100% conclusive that their baby did not have Down Syndrome, or Trisomy 21 defect.
22. NICHOLAS BIESTERFELD was born on February 6, 2018, and was diagnosed with Down Syndrome, or Trisomy 21 defect. This is the very defect the BIESTERFELDS had taken the ARIOSIA Test to discover.
23. NICHOLAS BIESTERFELD now requires 24-hour care, which must be delivered by his parents the BIESTERFELDS.
24. Following the birth, the BIESTERFELDS conducted an investigation as to why the ARIOSIA Test was wrong and created a false negative when their baby had Trisomy 21 in every cell of his body.
25. The BIESTERFELDS went on-line again in May 2018 to look at the ARIOSIA website and take a screenshot. They discovered the website they viewed in July 2017 was still up unchanged such that it still falsely advertised the ARIOSIA Test was 100% accurate. They took a screenshot of the same false advertisement they had viewed which lead them to buy

the ARIOSAS Test. (Attached hereto as Exhibit "A" is the online advertising screen shot from ARIOSAS's website from May 2018).

26. ARIOSAS trained its doctors that the ARIOSAS Test tests only fetal DNA. A test for only fetal DNA would be 100% accurate.
27. In fact, the ARIOSAS Test tests placental DNA. Placental DNA is a mixture from the mother and baby, such that the mixing creates mosaicism, where some cells from the mother are analyzed, which are normal and free of trisomy 21 defect, causing a negative test result as occurred here.
28. ARIOSAS did not disclose to treating physicians, including to those at DMG, that placental DNA was being tested, and not fetal DNA.
29. ARIOSAS knew of its misrepresentation and knew this representation would lead doctors to market the ARIOSAS Test for ARIOSAS and claim 100% accuracy to patients such as the BIESTERFELDS. This caused physicians to pass on this false information to the ultimate consumers and patients such as the BIESTERFELDS, causing them to believe the Test is 100% accurate.
30. The BIESTERFELDS discovered they had the option to conduct other testing had they not used the ARIOSAS Test. This available testing involved either a blood test to test the levels of pregnancy-associated plasma protein-A (PAPP-A), or an ultrasound to detect fluid at the back of the fetus' neck, or chorionic villus sampling (CVS), or amniocentesis. These tests could have been obtained within the time period allowed in Illinois for an abortion and when done together provided greater accuracy than the ARIOSAS Test.
31. If not for the conduct of ARIOSAS to provide false information passed through the doctors, from the ARIOSAS brochure and from the ARIOSAS website, the BIESTERFELDS would

have conducted other testing that would have discovered the fetus had trisomy 21 and terminated the pregnancy.

32. The birth of Nicholas Biesterfeld caused the BIESTERFELDS to have extraordinary expenses, which will occur at least until Nicholas' 18th birthday, and now are projected to be in excess of \$4,000,000. The birth of Nicholas Biesterfeld with the continued care caused and will cause emotional distress to the BIESTERFELDS.

**COUNT I—VIOLATION OF CONSUMER FRAUD AND DECEPTIVE
BUSINESS PRACTICES ACT**

33. Plaintiffs bring this cause of action pursuant to 815 ILCS 505/2, the Consumer Fraud and Deceptive Business Practices Act, in their individual capacities.

34. Section 1(e) defines a consumer:

(e) The term "consumer" means any person who purchases or contracts for the purchase of merchandise not for resale in the ordinary course of his trade or business but for his use or that of a member of his household.

35. ARIOSIA sold the ARIOSIA Test to Illinois consumers and patients of obstetrician-gynecologists through the physicians such as those at DMG .

36. The BIESTERFELDS were consumers of the ARIOSIA Test as they purchased the Test through DMG from ARIOSIA.

37. Section 2 of the Consumer Fraud and Deceptive Business Practices Act provides:

Sec. 2. Unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact, or the use or employment of any practice described in Section 2 of the "Uniform Deceptive Trade Practices Act", approved August 5, 1965, in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby. In construing this section consideration shall be given to the interpretations

of the Federal Trade Commission and the federal courts relating to Section 5 (a) of the Federal Trade Commission Act.

38. ARIOSAs made its false statements that were communicated to the BIESTERFELDS in the training provided to physicians such as those at DMG who treated MRS. BIESTERFELD, in the marketing in its brochure, and in its marketing on its website.

39. Defendants used unfair or deceptive acts or practices in one or more of the following ways:

- a. Fraudulently induced and misrepresented that the ARIOSAs Test is safe, fit, effective, and adequate for human use in detecting Down Syndrome;
- b. Misrepresenting that the ARIOSAs Test had a 100% accuracy rate in detecting Trisomy 21 abnormalities;
- c. Misrepresenting the limitations of and alternatives to the ARIOSAs Test;
- d. Misrepresenting that the ARIOSAs Test is more accurate than traditional first trimester screening tests;
- e. Misrepresenting that fetal DNA was being tested when, in actuality, only placental DNA was being tested;
- f. Misrepresenting the probability and rate at which the ARIOSAs Test could produce false negative results; and
- g. Using deceptive advertising to create the image, impression and belief by consumers and physicians that the use of the ARIOSAs Test was safe, reliable, and effective for detecting fetal chromosomal abnormalities, and having no reasonable grounds to believe such representations to be true.

40. ARIOSAs made the foregoing misrepresentations with the intent that Plaintiffs, and others similarly situated to Plaintiffs, would rely on such misrepresentations.

41. ARIOSAs knew or had reason to know that the foregoing misrepresentations were false, unfair or deceptive to Plaintiffs and others similarly situated to Plaintiffs.

42. Defendants made the foregoing misrepresentations or engaged in the foregoing deceptive acts and/or practices in the course of commerce.

43. Due to Defendants' misrepresentations and the inherently unfair practice of committing misrepresentations against the public by intentionally misrepresenting and concealing material information, Defendants' acts constitute unfair or deceptive acts and practices.
44. Defendants' actions are prohibited by the Consumer Fraud and Deceptive Business Practices Act.
45. The BIESTERFELDS relied on these false statements, causing the BIESTERFELDS to not use other testing as noted above that would have shown the presence of Trisomy 21 in the fetus.
46. But for the false statements of ARIOSA, the BIESTERFELDS would have terminated the pregnancy.
47. Because the BIESTERFELDS were not given the option to terminate the pregnancy, the birth of NICHOLAS BIESTERFELD has caused them to be responsible for extraordinary expenses until age 18 in the care and treatment of NICHOLAS in excess of \$4,000,000, and has caused and will cause future emotional distress.

WHEREFORE, the Plaintiffs, KATHLEEN BIESTERFELD, Individually as Mother & Next Best Friend of NICHOLAS BIESTERFELD, and RONALD BIESTERFELD, pray for entry of judgment against Defendants ARIOSA DIAGNOSTICS, INC., ARIOSA DIAGNOSTICS CLINICAL LABORATORY, and HARMONY PRENATAL TESTING for the damages incurred by Plaintiffs in excess of \$50,000, plus punitive damages, together with the costs of this action.

COUNT II—COMMON LAW FRAUD

48. Plaintiffs refer here, restate and re-allege paragraphs 1-32 as their paragraphs 48-80 of Count II.
81. ARISOA made false statements of material fact in one or more of the following ways:

- a. Fraudulently induced and misrepresented that the ARIOSIA Test is safe, fit, effective, and adequate for human use in detecting Down Syndrome;
 - b. Misrepresenting that the ARIOSIA Test had a 100% accuracy rate in detecting Trisomy 21 abnormalities;
 - c. Misrepresenting the limitations of and alternatives to the ARIOSIA Test;
 - d. Misrepresenting that the ARIOSIA Test is more accurate than traditional first trimester screening tests;
 - e. Misrepresenting that fetal DNA was being tested when, in actuality, only placental DNA was being tested;
 - f. Misrepresenting the probability and rate at which the ARIOSIA Test could produce false negative results; and
 - g. Using deceptive advertising to create the image, impression and belief by consumers and physicians that the use of the ARIOSIA Test was safe, reliable, and effective for detecting fetal chromosomal abnormalities, and having no reasonable grounds to believe such representations to be true.
82. ARIOSIA made the foregoing misrepresentations with the intent that Plaintiffs, and others similarly situated to Plaintiffs, would rely on such misrepresentations.
83. ARIOSIA knew or had reason to know that the foregoing misrepresentations were false, unfair or deceptive to Plaintiffs and others similarly situated to Plaintiffs.
84. Defendants made the foregoing misrepresentations or engaged in the foregoing deceptive acts and/or practices in the course of commerce.
85. Due to Defendants' misrepresentations and the inherently unfair practice of committing misrepresentations against the public by intentionally misrepresenting and concealing material information, Defendants' acts constitute unfair or deceptive acts and practices.
86. Defendants' actions are prohibited by the Consumer Fraud and Deceptive Business Practices Act.

87. The BIESTERFELDS relied on these false statements, causing the BIESTERFELDS to not use other testing as noted above that would have shown the presence of Trisomy 21 in the fetus.

88. But for the false statements of ARIOSAs, the BIESTERFELDS would have terminated the pregnancy.

89. Because the BIESTERFELDS were not given the option to terminate the pregnancy, the birth of NICHOLAS BIESTERFELD has caused them to be responsible for extraordinary expenses until age 18 in the care and treatment of NICHOLAS in excess of \$4,000,000, and has caused and will cause future emotional distress.

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COUNT III—NEGLIGENCE

90. Plaintiffs restate and re-allege paragraphs 1-32 of Count I as their paragraphs 90 through 123 of Count III.

124. ARIOSAs sold its ARIOSAs Test to the BIESTERFELDS through the DMG OBY-GYN clinic in 2017.

125. It was foreseeable to ARIOSAs that parents such as the BIESTERFELDS would rely upon the information ARIOSAs provided physicians such as at DMG; on reading ARIOSAs's brochures, and on reading ARIOSAs's website materials to purchase the ARIOSAs Test.

126. Further, it was foreseeable to ARIOSAs that the ARIOSAs Test would provide a false negative, thereby causing the parents to forego further testing in reliance on the ARIOSAs Test and forego termination of the pregnancy; whereby a baby would be born with Down Syndrome, and cause damage to the parents in the form of the extraordinary expenses until age 18 of providing for the baby as well as emotional distress to the parents.

127. ARIOSAs had a duty to Plaintiffs to exercise reasonable and ordinary care in designing, researching, testing, manufacturing, marketing, supplying, promoting, packaging, training, selling, and/or distributing the ARIOSAs Prenatal Test into the stream of commerce.

128. Notwithstanding the aforesaid duty, Defendants deviated from the exercise of reasonable and ordinary care in one or more of the following careless and negligent acts and/or omissions:


- a. Failed to inform Plaintiffs and others similarly situated that the ARIOSAs Test was not fit, effective, and/or adequate in detecting Down Syndrome in the level advertised and marketed;
- b. Failed to represent to Plaintiffs and others similarly situated that the ARIOSAs Test did not have a 100% accuracy rate in detecting abnormalities of Trisomy 21;
- c. Failed to represent to Plaintiffs and others similarly situated the limitations of and alternatives to the ARIOSAs Test;
- d. Failed to represent to Plaintiffs and others similarly situated that the ARIOSAs Test is less accurate than traditional first trimester screening tests;
- e. Failed to represent to Plaintiffs and others similarly situated that fetal DNA was alone being tested when, in actuality, placental DNA was being tested; and
- f. Failed to include in its training to physicians, in its brochure and in its online marketing materials Plaintiffs and others similarly situated the probability and rate at which the ARIOSAs Test could produce false negative results.

129. But for the negligence of ARIOSIA in testing, marketing and advertising the ARIOSIA Test, the BIESTERFELDS would have terminated the pregnancy but lost the choice to terminate the pregnancy.

130. The birth of NICHOLAS BIESTERFELD has caused them to be responsible for extraordinary expenses until age 18 in the care and treatment of NICHOLAS in excess of \$4,000,000 and has caused and will cause future emotional distress to the BIESTERFELDS.

WHEREFORE, the Plaintiffs, KATHLEEN BIESTERFELD, Individually as Mother & Next Best Friend of NICHOLAS BIESTERFELD, and RONALD BIESTERFELD, pray for entry of judgment against Defendants ARIOSIA DIAGNOSTICS, INC., ARIOSIA DIAGNOSTICS CLINICAL LABORATORY, and HARMONY PRENATAL TESTING for the damages incurred by Plaintiffs in excess of \$50,000 together with the costs of this action.

Respectfully submitted,
VINKLER LAW OFFICES, LTD.

A handwritten signature in black ink, appearing to read "Jerome A. Vinkler". The signature is fluid and cursive, with the first name "Jerome" and last name "Vinkler" clearly distinguishable.

Jerome A. Vinkler

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